Maine Department of Health and Human Services

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TO: Interested Parties

FROM: J. Michael Hall, Director, Office of MaineCare Services

SUBJECT: Final Rule: Department of Health and Human Services**,** 10-144, Chapter 275, Section 2, Reporting of Prescription Drug Marketing Costs

DATE: September 29, 2006

This letter gives notice of an adopted rule: Department of Health and Human Services**,** 10-144, Chapter 275, Section 2, Reporting of Prescription Drug Marketing Costs. The Department held a public hearing on May 15, 2006 at 442 Civic Center Drive, Augusta, Maine. The comment deadline was June 1, 2006.

This rule was initially proposed in conjunction with 10-144, Chapter 275, Section 1 entitled Prescription Drug Clinical Trial Reporting. However, due to substantive revisions made to proposed Section 1 (filed jointly with the Office of the Attorney General) as a result of public comments received, the two Offices have determined that a reposting of Section 1 is necessary in order to allow further public comment. Hence, Section 2 has been adopted independently from Section 1.

The Section 2 rule requires manufacturers and labelers of prescription drugs to report gifts and specific marketing costs to the Department in order to assist the State in its role as a purchaser of prescription drugs and an administrator of prescription drug programs. This will enable the State to determine the scope of prescription drug marketing costs and their effect on the cost, utilization, and delivery of health care services and strengthen the role of this State as guardian of the public interest.

Rules and related rulemaking documents may be reviewed and printed from the Office of MaineCare Services website at http://www.state.me.us/bms/rules/gen_other_rules.htm or, for a fee, interested parties may request a paper copy of rules by calling 207-287-9368. For those who are deaf or hard of hearing and have a TTY machine, the TTY number is 1-800-423-4331.

If you have any questions regarding the policy, please contact your Provider Relations Specialist at 624-7539 option 8, or 1-800-321-5557 option 8, or TTY: (207) 287-1828 or 1-800-423-4331.

Notice of Agency Rule-making Adoption

AGENCY: Department of Health and Human Services, Office of MaineCare Services

CHAPTER NUMBER AND TITLE: Maine State Services Manual**,** 10-144, Chapter 275, Section 2, Reporting of Prescription Drug Marketing Costs

ADOPTED RULE NUMBER:

CONCISE SUMMARY: The rule requires manufacturers and labelers of prescription drugs to report gifts and marketing costs to the Department in order to assist the State in its role as a purchaser of prescription drugs and an administrator of prescription drug programs. This will enable the State to determine the scope of prescription drug marketing costs and their effect on the cost, utilization, and delivery of health care services and furthering the role of this State as guardian of the public interest.

See http://www.maine.gov/bms/rules/gen_other_rules.htm for rules and related rulemaking documents.

EFFECTIVE DATE: October 6, 2006

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10-144
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Chapter 275

SECTION 2 REPORTING REQUIREMENTS FOR PHARMACEUTICAL MANUFACTURERS AND LABELERS **ESTABLISHED 10/6/06**

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SECTION 2 REPORTING OF PRESCRIPTIOIN DRUG MARKETING COSTS

2.01 STATUTORY AUTHORITY AND PURPOSE

These regulations are adopted pursuant to 22 M.R.S.A.§2698-A and apply to any product dispensed with a prescription and covered by a State of Maine pharmacy benefit. Marketing costs for prescription drugs in this State must be reported to the Department of Health and Human Services (DHHS) in order to assist the State in its role as a purchaser of prescription drugs and an administrator of prescription drug programs, thereby enabling the State to determine the scope of prescription drug marketing costs and their effect on the cost, utilization, and delivery of health care services and furthering the role of this State as guardian of the public interest.

2.02 DEFINITIONS

2.02-1 **Affiliate** means a business entity that has a relationship with a second business entity if, directly or indirectly, one business entity controls or has the power to control the other business entity, or a third party controls or has the power to control both of the business entities. A business entity controls another if it owns fifty percent (50%) or more of the equity interest or exercises a controlling influence over the management and policies of the other.

2.02-2 **Bona Fide Clinical Trial** means any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause and effect relationship between a medical intervention and a health outcome.

2.02-3 **Labeler** means a person or entity that (a) receives prescription drugs or biological products from a manufacturer or wholesaler; (b) repackages the drugs or biological products for later resale; and (c) has a labeler code from the federal Food and Drug Administration under section 207.20 of Title 21 of the Code of Federal Regulations.

2.02-4 **Manufacturer** means (a) a manufacturer of prescription drugs or biological products, and (b) affiliates of the manufacturer.

2.02-5 **Marketing** means advertising and promotional activities, including, but not limited to, the activities described in 2.04.

2.02-6 **Significant educational, scientific or policy-making conference or seminar** means an educational, scientific or policy-making conference or seminar that offers continuing medical education credit, features multiple presenters on scientific research, or is authorized by the sponsoring association to recommend or make policy.

2.03 REPORTING – GENERAL REQUIREMENTS

A manufacturer or labeler of prescription drugs dispensed in this State that employs, directs or utilizes marketing representatives in this State must annually report marketing costs for

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2.03 **REPORTING – GENERAL REQUIREMENTS (Cont.)**

prescription drugs in this State as described in this rule, in the form and manner provided by the Department.

2.03-1 Timing

A manufacturer or labeler of prescription drugs that directly or indirectly distributes prescription drugs for dispensation to residents of this State shall file an annual report with the Department by July 1 of each year as of July 1, 2007. The report will contain the information required by statute for the prior calendar year; i.e., from January 1 through December 31 of the prior year.

In the report due July 1, 2007, manufacturers and labelers should report data by quarters. If any or all data for the first three quarters of 2006 are not available, then manufacturers and labelers may substitute an explanation of why the data are not available for the data itself.

Data may be reported in an electronic format that is satisfactory to the Department.
In general, manufacturers and labelers should use the date of the activity to assign a reporting period – e.g., if a marketing campaign spans two reporting periods (quarters for the first year of reporting or calendar years subsequently), the cost of the campaign should be prorated by reporting period. Grant amounts should be reported for the period in which the money is provided, and do not need to be allocated over the life of the grant.

2.03-2 Fee

A one-thousand dollar ($1000.00) fee payable to "Treasurer, State of Maine", must accompany the annual report, unless the report is filed electronically, in which the fee must be sent within five (5) business days. The fee may be paid by check to the Maine Department of Health and Human Services or wired, pursuant to departmental instructions. The Department may reduce this fee at its discretion if the Department finds that administrative costs are less than anticipated.

2.04 **CONTENT OF ANNUAL REPORT BY MANUFACTURER OR LABELER**

The required annual report must include the information listed below as it pertains to marketing activities conducted within Maine. Appendix A contains more detailed information related to the Department's requirements for the "Annual Report."

2.04-1 Advertising, Marketing and Direct Promotion

All expenses associated with advertising, marketing and direct promotion of prescription drugs through radio, television, magazines, newspapers, direct mail and telephone communications made to residents of this State, including payments or grants directed to or earmarked for use in Maine, except for expenses associated with

2.04 **CONTENT OF ANNUAL REPORT BY MANUFACTURER OR LABELER (Cont.)**

advertising and promotional activities purchased for a regional or national market that includes advertising within this State.

All costs must be determined using generally accepted accounting principles (GAAP).

2.04-2 Economic Benefits for Providers

With regard to all persons and entities licensed to provide health care in this State, including health care professionals and persons employed by them in this State, carriers licensed under Title 24 or Title 24-A, health plans and benefits managers, pharmacies, hospitals, nursing facilities, clinics and other entities licensed to provide health care under this Title must provide the following information:

A. All expenses directly associated with educational or information programs, materials and seminars and remuneration to such persons and entities for promoting or participating in educational or informational sessions, regardless of whether the manufacturer or labeler provides the educational or informational sessions or materials. This includes but is not limited to:

- Support for independent or continuing medical education programs (IME or CME) to the extent of participation by such persons and entities, including payments to medical education companies;
- Printing costs of patient education materials and disease management materials distributed to such persons and entities. Design and other production costs also must be reported for materials designed specifically for Maine users;
- Payment of consulting fees and expenses directly or indirectly to such persons and entities, subject to exceptions in Section 2.05 below;
- Payments made directly or indirectly to such persons and entities for participation in speakers' bureaus and honoraria or other payments for time while speaking at or attending meetings, lectures or conferences;
- Payments made directly or indirectly to such persons or entities for writing articles or publications;
- Charitable grants, either directly or earmarked, to such persons and entities, even if unrestricted;
- Payments made directly or indirectly to such persons or entities in connection with market research surveys or other activities undertaken in support of developing advertising and/or marketing strategies.

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2.04 **CONTENT OF ANNUAL REPORT BY MANUFACTURER OR LABELER (Cont.)**

B. Costs of food, entertainment, gifts valued at more than twenty-five dollars ($25) per day, and anything provided to such persons or entities for less than market value. The Department will treat gifts to an office or office staff as gifts to the prescriber, clinic or facility. If the gift is a sixty dollars ($60) luncheon for an office of three physicians and three non-prescribing office staff, the gift amount shall be attributed in whole to the clinic or facility and is reportable;

C. Costs of trips and travel provided to such persons or entities;

D. Costs of product samples provided to such persons or entities, except for samples and starter kits that will be distributed free of charge to patients; and

E. Costs of free or in-kind services provided to such persons or entities.

2.04-3 Costs of Employees/Contractors

All forms of compensation, including benefits, to all employees and all forms of payment to all contractors of the manufacturer or labeler who directly or indirectly engage in the advertising, marketing or promotional activities listed in paragraphs 2.04-1 and 2.04-2. The cost reported under this subsection must reflect only that portion of compensation or payment to employees or contractors that pertains to activities within this State or to recipients of the advertising, marketing or promotional activities who are residents of or are employed in this State, except for costs associated with advertising, marketing or promotion only for a regional or national market. All costs must be determined using Generally Accepted Accounting Principles (GAAP).

In calculating reportable employee costs attributed to Maine-directed advertising, marketing and promotional activities, manufacturers and labelers shall include that portion of compensation for all applicable employees who are directly or indirectly engaged in advertising, marketing or promotional activities, including direct supervisors of those directly engaged in such activities, regardless of place of residence or primary office location. Personnel providing only administrative or incidental support are not directly or indirectly engaged in advertising, marketing or promotional activities as those terms are intended.

The manufacturer or labeler may elect to apply a standard benefit rate (health insurance, pension, vacation, sick) to calculate personnel costs.

If the employee or a contractor provides such services to six (6) or more states (e.g. to the New England region or nationwide) without particular emphasis on Maine, his or her compensation attributable to direct or indirect advertising, marketing and promotional activities can be allocated by dividing by the number of states served, unless data related to advertising, marketing or promotion activity particular to Maine are reasonably available. If the employee or contractor provides such services to two or

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2.04 **CONTENT OF ANNUAL REPORT BY MANUFACTURER OR LABELER (Cont)**

more but fewer than six (6) states, the manufacturer shall report information based on data that are particular to Maine or, if data are not available, the proportion of effort directed toward Maine.

If companies collaborate, each manufacturer or labeler should report its portion of applicable costs.

2.04-4 Company Contact Information

Each company subject to the provisions of this section must report as part of its annual report the name and contact information of the individual responsible for the company's compliance with the provisions of this section.

2.05 **EXCEPTIONS**

The following expenses are not subject to the requirements of this section:

- Marketing expenses of twenty-five dollars ($25) or less (per day);
- Reasonable compensation and reimbursement for expenses in connection with a bona fide clinical trial of a new vaccine, therapy, treatment, or indication; and
- Scholarships and reimbursement of expenses for attending a significant educational, scientific or policy-making conference or seminar of a national, regional or specialty medical or other professional association if the recipient of the scholarship is chosen by the association sponsoring the conference or seminar.

2.06 **DEPARTMENT REPORT**

2.06-1 Annual Report

The Department shall provide an annual report, providing information in aggregate form, on prescription drug marketing expenses, to the Maine Legislature and the Attorney General by November 30th of each year, starting calendar year 2007. In preparing such annual report, the Department shall designate a person to review the report before publication to ensure against disclosure of a trade secret of any manufacturer or labeler that has filed a report in compliance with these rules. As part of such determination, such person may contact the manufacturer or labeler.

2.06-2 Biannual Analysis

By January 1, 2008, and every two (2) years after that date, the Department shall provide a report to the Legislature and the Attorney General, providing information in aggregate form, containing an analysis of the data submitted to the Department,

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2.06 **DEPARTMENT REPORT (Cont.)**

including the scope of prescription drug marketing activities and expenses and their effect on the cost, utilization and delivery of health care services and any recommendations with regard to marketing activities of prescription drug manufacturers and labelers as required by 22 M.R.S.A. § 2698-A(6). In preparing such report, the Department shall designate a person to review the report before publication to ensure against disclosure of a trade secret of any manufacturer or labeler that has filed a report in compliance with these rules. As part of such determination, such person may contact the manufacturer or labeler.

2.07 **CONFIDENTIALITY, PUBLIC INFORMATION**

2.07-1 Confidentiality of Annual Drug Company Reporting

Notwithstanding any other provision of law to the contrary, information submitted to the Department pursuant to 22 M.R.S.A. § 2698-A is confidential and is not a public record as defined in 1 M.R.S.A. § 402(3).

2.07-2 Public Availability of Aggregate Data

Data compiled in aggregate form by the Department for the purposes of reporting as required by 22 M.R.S.A. § 2698-A are a public record as defined in 1 M.R.S.A. § 402(3), as long as the compilation does not reveal trade information that is protected by state or federal law.

2.08 **PENALTY**

The Attorney General may enforce 22 M.R.S.A. § 2698-A in a civil action. A manufacturer or labeler that fails to provide a timely, complete and accurate report as required in 22 M.R.S.A §2698-A commits a civil violation for which a fine of one thousand dollars ($1,000) plus costs and attorney fees may be adjudged.

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APPENDIX A – SPECIFIC REPORTING REQUIREMENTS

For each manufacturer or labeler, for each gift that meets the requirements for mandated reporting, the reporter must provide the following information:

- Name of Manufacturer or Labeler
- Date of Payment/Gift
- Name of Recipient
- Type of Recipient (e.g., clinic, doctor, hospital, pharmacist, university, other prescriber, benefits manager, health plan, nursing facility, psychiatric hospital, other healthcare provider)
- Credentials of Recipient, if applicable (e.g., APRN, DDS, DO, DPM, DVM, MD, PA)
- Nature of Payment (e.g., book, cash or check, donation, food, grant, lodging, transportation, samples)
- Primary Purpose of Payment (e.g., consulting, professional education, charitable grant, speaker fee or payment)
- Monetary Value of Payment

For each manufacturer or labeler, for each advertising, marketing or direct promotion activity that meets the requirements for mandated reporting, the reporter must provide the following information:

- Name of Manufacturer or Labeler
- Date(s) of Activity
- Type of Activity (e.g., advertising, marketing, direct promotion, market research survey, patient education including materials such as disease management information; materials/consulting to promote new uses of drugs)
- Medium (e.g., radio, television, magazines, newspapers, direct mail, telephone)
- Name of Medium, if applicable (e.g., TV or radio station, newspaper, magazine)
- Product Marketed (e.g., name of drug, general brand/company awareness)
- Target Audience (e.g., general public, prescribers)
- Cost of Activity

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APPENDIX A – SPECIFIC REPORTING REQUIREMENTS (Cont.)

For each manufacturer or labeler, for all employees and/or contractors that meet the requirements for mandated reporting, the reporter must provide the aggregate costs for these services as determined using GAAP.